II. REMARKS

A. Status of the Claims

Claims 6-7, 13-16 and 24 are currently pending. Claims 1-5, 9-12, 17-23 have been cancelled without prejudice. Claims 6 and 24 have been amended without prejudice. Support for these amendments can be found specifically in originally filed claim 21 and in the Examples of the specification. It is respectfully submitted that no new matter has been added by virtue of this amendment.

B. Claim rejection under 35 U.S.C. §103

1. Goldie et al.

In the Office Action, the Examiner rejected claims 6-8, 13-16, 21 and 24 under 35 U.S.C. §103(a) over Goldie et al. (U.S. 4,844,909).

This rejection is traversed. Applicants respectfully submit that in view of the Goldie reference, one skilled in the art would not be motivated to administer the dosage form disclosed therein "at a dosing interval of about 24 hours."

"[A] proper analysis under § 103 requires, inter alia, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success." Noelle v. Lederman, 355 F.3d 1343, 1352 (Fed. Cir. 2004), citing In re Vaeck, 947 F.2d 488, 493 (Fed. Cir. 1991).

In following the above analysis, Applicants respectfully refer the Examiner to the Goldie reference at column 2, lines 4-10, which recites that although the Goldie formulations "give peak plasma levels of hydromorphone between 2 and 4 hours after administration, they still afford therapeutic levels of hydromorphone in vivo over at least a 12 hour period, and may therefore be used on a ***twice daily basis***." (Emphasis added.) Given this teaching of the Goldie reference,

Applicants respectfully submit that one skilled in the art would not be motivated to administer the formulations disclosed therein at a dosing interval of about 24 hours. Further, Applicants submit that one skilled in the art would not have an expectation of success of providing a therapeutic effect for at least the 24 hour dosing interval, as Goldie et al., specifically teach that the formulations disclosed therein are "used on a twice daily basis."

In view of the above, Applicants respectfully request that the rejection under 35 U.S.C. §103(a) be removed.

III. CONCLUSION

In view of the amendments made and arguments presented, it is respectfully requested that the Examiner's rejections be withdrawn. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application. An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____

Robert L. Paradiso
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940